Docket No.: 13173-00022-US

(PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Ute Heim et al.

Application No.: 10/565,221

Confirmation No.: 7312

Filed: February 28, 2006

Art Unit: 1638

For: EXPRESSION CASSETTES FOR THE BI-

DIRECTIONAL TRANSGENIC EXPRESSION

OF NUCLEIC ACIDS IN PLANTS

Examiner: Page, Brent T.

# RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the restriction requirement set forth in the Office Action mailed March 20, 2008, Applicants hereby provisionally elect Group I, claims 1-4, 8-14 and 19-29, drawn to SEQ ID NO: 2 for further prosecution with traverse. Reconsideration and withdrawal of the restriction requirement is strongly urged for the following reasons.

### The Claimed Inventions Share a Special Technical Feature

Because this application is a national stage filing pursuant to 35 U.S.C. § 371, unity of invention under PCT Rule 13.1 and 13.2 is the applicable standard. An application "shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." (PCT Rule 13.1). Unity of invention is fulfilled "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical feature. The expression 'special technical feature' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (PCT Rule 13.2).

Docket No.: 13173-00022-US

The Examiner notes that the claims are related by the technical feature of promoter sequences. However, the Examiner argues that this technical feature is not special because it is known in the art, citing to Benfey *et al.* (Science, 250: 959-966, hereinafter "Benfey"). In response to Applicants' traversal to the Restriction Requirement dated October 30, 2007, the Examiner argues that the claims do not contain any limitation that corresponds to a bidirectional promoter, the special technical feature linking the claims argued by Applicants. Applicants respectfully disagree with the Examiner's characterization of the invention.

As discussed in Applicants' Response dated November 29, 2007, Benfey discloses the characterization of the 35S promoter of the cauliflower mosaic virus. Benfey, however, does not disclose a promoter that has a bidirectional promoter activity.

As disclosed throughout the specification, the general inventive concept of the present application relates to an expression cassette or vector containing a promoter having bidirectional activity. See, for example, Specification at page 1, lines 3-5 and lines 26-28 (regulatory sequences which result in transcription of the upstream and downstream DNA sequences in both directions), page 2, lines 24-27, and Examples 4, 7, 8 and 9 at pages 31-33. This is further evidenced by the title of the present application, which recites "bidirectional transgenic expression" to reflect the general inventive concept of the present application. Additionally, opposite to the Examiner's allegation, the claims clearly describe that the regulatory sequence in the expression cassette is a bidirectional promoter. Specifically, claims 1 and 13, the two independent claims in the present application, recites that the regulatory element or regulatory sequence "is disposed between two nucleic acid sequences and is heterogeneous in relation to said nucleic acid sequences and is functionally linked to said nucleic acid sequences in such a way that the expression of two different ribonucleic acid sequences is brought about in at least one plant cell." It is respectfully submitted that the above-mentioned claim language is sufficiently clear to draw a distinction between the promoter used in the present application and the promoters known in the art such as the promoters described in Benfey. Therefore, Benfey does not disclose the special common technical feature of the present application, a promoter that would result in transcription of DNA sequences in both directions. Accordingly, unity of invention is fulfilled because the claims of the present application share a

common special technical feature that makes a contribution over the prior art. Thr restriction requirement is improper.

Docket No.: 13173-00022-US

Moreover, Applicants believe that there is no undue burden on the Examiner to search both Groups together. As stated in § 803 of the M.P.E.P. "[i]f the search and examination of the entire application can be made without serious burden, the examiner <u>must</u> examine it on the merits, even though it includes claims to independent or distinct inventions." (M.P.E.P. § 803, emphasis added). As discussed above, all of the claims share a common technical feature of a bidirectional promoter. Thus, the same art and field of search relevant to Group I (directing to plant organism) would be also relevant to Group II (directing to non-human, non-plant organism). No undue burden would be required in examining these two Groups together. Accordingly, Applicants respectfully request that the Examiner reconsider the restriction requirement and examine all the claims in one application.

## The International Examiner Found Unity of Invention

Furthermore, as mentioned in the Response dated November 29, 2007, unity of invention was found during the international stage. As shown in the International Preliminary Report on Patentability and the International Search Report, all claims were searched and examined together. Thus, application of PCT Rules 13.1 and 13.2 by the International Examiners shows that unity exists. Since the search has already been conducted by the International Search Authority and the International Examination Authority and no lack of unity of invention has been found, for this additional reason, there would be no undue burden on the Examiner to examine both Groups in one application.

### CONCLUSION

For at least the above reasons, Applicants respectfully request that the restriction requirement be reconsidered and withdrawn.

Applicants reserve all rights to pursue the non-elected species in one or more divisional application.

Applicants are submitting their response within the one-month response period. No fee is believed due. However, if any fee is due, the Director is hereby authorized to charge our Deposit

Account No. 03-2775, under Order No. 13173-00022-US from which the undersigned is

authorized to draw.

Respectfully submitted,

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